

Exhibit G

1 IN THE UNITED STATES DISTRICT COURT
2 FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
3 CHARLESTON DIVISION

4

5

IN RE: ETHICON, INC., MASTER FILE NO.
6 PELVIC REPAIR SYSTEM 2:12-MD-02327
PRODUCTS LIABILITY LITIGATION
7 MDL 2327
8 JOSEPH R. GOODWIN
U.S. DISTRICT JUDGE

9

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12 MARY AND FRANK SHELTON PLAINTIFFS

13

14 VS . CASE NO. : 2:12-cv-01707

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16 ETHICON, INC., ET AL. DEFENDANTS

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Ridgeland, Mississippi

BEGINNING THE APPROXIMATION TO THE GATE

111 W. 111st, NYC, USA

1 A P P E A R A N C E S

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S T I P U L A T I O N

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It is hereby stipulated and agreed by

respective attorneys of record, that this

deposition may be taken at the time and place

hereinbefore set forth, by AMY M. KEY, Court

Reporter and Notary Public, pursuant to the Rules;

That the formality of reading and

signing is specifically RESERVED;

That all objections, except as to the

form of the questions and the responsiveness of

the answers, are reserved until such time as the

deposition, or any part thereof, may be used or

sought to be used in evidence.

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4 EXAMINATION

5 BY MR. BOWMAN:

6 Q. Dr. Thames, my name is Mike Bowman. We've
7 met previously. Thank you for joining us this
8 morning.

9 We are here today to talk about your
10 report in the case -- Mary Shelton case; is that
11 right?

12 A. Yes, sir.

13 Q. Do you know how many pieces of mesh were
14 involved in your analysis of Ms. Shelton's case?

15 A. One.

16 Q. Do you know if that was a TVT mesh or a
17 Gyne mesh?

18 A. Let's see. T.V.T.

19 Q. And it was supplied to you by Dr. Kevin
20 Ong?

21 A. Yes, sir.

22 Q. As far as you know, he split the sample
23 with plaintiff's counsel before he did anything to
24 it?

25 A. Yes, sir.

1 Q. And all of the cleaning steps outlined on
2 page 2 of your report were followed to the letter to
3 the best of your knowledge?

4 A. Absolutely.

5 Q. On page 3, we see a figure 2 of some
6 pristine Prolene mesh before cleaning and in
7 figure 3 we see some -- we see a picture of the
8 sample that is representative of Ms. Shelton's case;
9 is that correct?

10 A. Yes, sir.

11 Q. Do you know why we're seeing a picture of
12 pristine Prolene mesh instead of TVT?

13 A. No, sir, but it's the same material.

14 Q. Do you make a determine in your mind as to
15 whether or not it's Prolene mesh or TVT mesh?

16 A. Prolene mesh is the same as TVT mesh.

17 Q. Chemically at least, correct?

18 A. Correct.

19 Q. And that's as far as your opinion goes in
20 this case?

21 A. Yes, sir.

22 Q. You're not worried about the diameters of
23 the monofilaments or anything like that?

24 A. No, sir.

25 Q. With respect to Ms. Shelton's mesh, did

1 you find any evidence of Prolene oxidation on her
2 mesh?

3 A. No, sir.

4 Q. And what were the methods that you used to
5 come to that conclusion?

6 A. FTIR, light microscopy and scanning
7 electron microscopy.

8 Q. And did you use those --

9 A. Excuse me. And the cleaning steps of
10 figure 1.

11 Q. I see. Did you do any mechanical testing
12 or tensile testing on Ms. Shelton's mesh?

13 A. No. There was not enough sample.

14 Q. Do you know if anybody at all did any
15 testing just in their own subjective view of whether
16 or not the pristine mesh and Ms. Shelton's mesh
17 behaved the same after the cleaning process?

18 A. I wouldn't have any idea what someone else
19 has done.

20 Q. Did you do it?

21 A. Do what now?

22 Q. Did you compare Ms. Shelton's mesh after
23 the cleaning process to a piece of pristine mesh and
24 just sort of hold them in your hand and see if there
25 was any give?

1 A. You're talking about mechanical properties
2 by field?

3 Q. Yes, sir.

4 A. No, sir.

5 Q. You did not do that? Did you direct
6 anybody to do that?

7 A. No, sir. There's not enough material for
8 that, sir.

9 Q. Thank you. With respect to figure 4,
10 figure 4 is a photograph of a Ms. Shelton's mesh
11 before it was cleaned; is that right?

12 A. Yes, sir.

13 Q. It actually been soaked in some water and
14 desiccated before it was sent to you; is that right?

15 A. Yes, sir.

16 Q. And this is at 200 times magnification,
17 and this is not representative of the entire mesh
18 sample; is that right?

19 A. Did you say it's not representative of the
20 entire sample?

21 Q. That was a misstatement. This is not --
22 the photograph itself is not of the entire mesh
23 sample. This is 200 times magnification at one
24 point on the mesh sample?

25 A. Yes, sir.

1 Q. In figure 5, we see the status of the mesh
2 after the first cleaning; is that right?

3 A. Yes, sir.

4 Q. And this is after a good deal of the
5 protein has been removed, but not all of it; is that
6 right?

7 A. That's correct, sir.

8 Q. In this photograph, do you see flakes of
9 little bits of mesh coming off in several -- I'm
10 sorry. That was a bad question.

11 Do you see flakes on this photograph,
12 Doctor?

13 A. Yes, sir.

14 Q. And have you made a determination as to
15 what those flakes are?

16 A. Yes, sir.

17 Q. What is that determination?

18 A. Proteins.

19 Q. With respect to Ms. Shelton's mesh, this
20 actually doesn't have any blue dye in it, does it?

21 A. No, sir. This is an all-clear sample.

22 Q. Have you made any visual determination, as
23 you have in the past, as to whether or not those
24 flakes on the outside of the mesh are proteinaceous
25 or oxidized polypropylene?

1 A. We've done FTIR spectroscopy and scanning
2 electron microscopy as well as light microscopy,
3 what you see here. And the FTIR says they're
4 proteins. There's no indication that Prolene was
5 oxidized in any way.

6 Q. I understand you did an FTIR, and I
7 understand you did SEM. But with respect to your
8 opinions regarding the presence of translucent
9 flakes on blue monofilaments, you can't make that
10 opinion in Ms. Shelton case, can you?

11 A. Not in this case, no, sir.

12 Q. Because the monofilaments themselves are
13 clear, correct?

14 A. That is correct.

15 Q. Looking at figure 7, --

16 A. Yes, sir.

17 Q. -- this is an FTIR of the clear fiber
18 before cleaning; is that correct?

19 A. Yes, sir.

20 Q. So this is right when it came to you.
21 Nothing else was done to it after Mr. Ong sent it on
22 to you?

23 A. That's correct.

24 Q. And you have a photograph in the upper
25 right-hand corner of the exact point where the FTIR

1 was taken on a monofilament, correct?

2 A. At the crosshairs, yes, sir.

3 Q. And in this FTIR, you have identified
4 where polypropylene is showing up --

5 A. Yes, sir.

6 Q. -- on this reading?

7 And you've also identified where the
8 protein Amide I carbonyl stretch is?

9 A. Yes, sir.

10 Q. And that appears to be at 1652; is that
11 right?

12 A. Yes, sir.

13 Q. And you've also identified where the
14 protein Amide N-H stretch is. And that is at 3347;
15 is that right?

16 A. In that region, yes, sir.

17 Q. For this FTIR, have you taken into account
18 any shifts that might occur because of the presence
19 of oxidized polypropylene or other proteins in
20 there?

21 A. Yes, sir, I've taken all that into
22 consideration.

23 Q. And is it your understanding that the
24 shifts themselves would be negligible?

25 A. Yes, sir.

1 Q. That they would be -- can you explain to
2 me what you mean by negligible?

3 A. The shift might be the width of a pencil
4 dot.

5 Q. A pencil dot on this FTIR that we're
6 seeing in figure 7?

7 A. Yeah.

8 Q. So the shift would be -- it wouldn't be
9 70 points? It would be just be --

10 A. Oh, absolutely not.

11 Q. It wouldn't be 150 either?

12 A. No, sir. No, sir.

13 Q. It would just be one or two? Okay. And
14 have you done any research on any shifting
15 associated with oxidized polypropylene to confirm
16 that?

17 A. To specifically -- the shift is going to
18 depend upon what's in its environment and what's
19 affecting it and having an effect on the C=O, the
20 polarity of it. And that's well established in the
21 literature. There may be some slight shifts in
22 cases like that, but there's no need for me to do
23 the research on it. It's published in literature.

24 Q. Nonetheless, it's your understanding that
25 if there was a shift it would be negligible?

1 A. I think it's a good term.

2 Q. Thank you. On figure 8, we are looking at
3 the before cleaning of Ms. Shelton's mesh overlaid
4 with the collagenase reference spectra?

5 A. Yes, sir.

6 Q. Identified at type VII high purity; is
7 that right?

8 A. Yes, sir.

9 Q. And this is an FTIR of the clear fibers;
10 is that right?

11 A. Well, that's the only fiber we had was
12 clear, yes, sir.

13 Q. My question was a little confusing. But
14 in this case, you didn't overlay the collagenase
15 with protein that was between the interstices of the
16 mesh; is that right?

17 A. That's right.

18 Q. In this case, you took the FTIR from the
19 before cleaning and you overlaid it with the
20 collagenase; is that right?

21 A. Yes, sir.

22 Q. Is it your opinion that where the N-H
23 peaks are that that is the only thing that would
24 show up in that area?

25 A. That is the only thing that would show up

1 in that area?

2 Q. Yes, sir.

3 A. No. You may have some other extraneous
4 materials, but that's primarily where the N-H --
5 you'll see the peak is very sharp, and it depends
6 upon the amount of material that's present.

7 Q. So the peak on the collagenase is sharp,
8 correct?

9 A. Yes, sir.

10 Q. On the --

11 A. On the pure sample.

12 Q. On the pure sample?

13 A. Uh-huh (affirmative response).

14 Q. And we're talking about the range between
15 34- and 3200 for that peak?

16 A. That's about right, yes, sir.

17 Q. And what you've identified as the Amide
18 group -- the N-H group on the Amide group?

19 A. Yes, sir.

20 Q. You identified it at 3347, correct?

21 A. Yes, sir.

22 Q. And do you know if there was presence of
23 oxidation on the Prolene itself, if it would show up
24 in that same general area?

25 A. I do not have any data that I know of that

1 would -- the oxidation product that I'm looking for
2 is a C=O bond. That is the bond where there's
3 rupture of the fiber. And until you get to that
4 point, everything else is irrelevant.

5 Q. So there are at least two -- strike that.

6 Doctor, are you saying that an O-H group
7 on a polypropylene chain is not evidence of
8 oxidation?

9 A. It's not relevant to this case in the
10 sense that we're talking about whether or not it
11 decomposes, whether it becomes friable, whether it
12 loses its physical properties. And the only time
13 that occurs or begins to occur is when a carbonyl
14 bond is formed. Because when a carbonyl bond is
15 formed, you will have bond rupture of the Prolene.
16 And we don't see that.

17 I can't say that at some point in time a
18 hydroxyl group might be present, but that is
19 irrelevant to me. What is relevant is the carbonyl
20 group that's present, the C=O. That's when the
21 breaking of the bonds begin to occur.

22 Q. So the presence of a C=O on polypropylene
23 is evidence of loss of molecular weight?

24 A. Yes, sir, bond rupture.

25 Q. Is the presence of an O-H group on

1 polypropylene the evidence of loss of molecular
2 weight?

3 A. No, sir.

4 Q. Why not?

5 A. Because it doesn't cause bond rupture.

6 Q. So the oxygen itself is actually in the
7 area of not only the hydrogen that's associated with
8 the polypropylene but also associated with the
9 carbon, correct? So the oxygen is actually in the
10 same area?

11 A. If you have a bond to a hydroxyl group to
12 attach to Prolene, there will be a carbon-to-oxygen
13 bond, but it doesn't cause bond rupture.

14 Q. Would you consider the O-H group an
15 intermediate to carbonyl formation?

16 A. It could be an intermediate, but it
17 doesn't cause bond rupture. So, therefore, since we
18 don't have any oxidation, the likelihood of having
19 hydroxyl group is remote.

20 Q. Could the hydroxyl group form after the
21 carbonyl had been formed in Ms. Shelton's case?

22 A. No -- well, yes, I guess it could. But
23 the issue here is we don't get any bond rupture. We
24 don't get any carbonyls.

25 Q. So because you don't see carbonyls, the

1 N-H group is not -- I'm going to withdraw that
2 question.

3 In Ms. Shelton's case, the fact that there
4 might be an O-H group associated with the
5 polypropylene isn't necessarily important to your
6 findings in this case; is that right?

7 A. Absolutely, because I'm interested in the
8 chemical reaction that would take place, possibly
9 take place because of rupture of the fiber. That's
10 when your properties begin to diminish and only
11 then.

12 Q. So an O-H group, it could be an
13 intermediary --

14 A. It could be.

15 Q. -- to the carbonyl formation?

16 A. It could be.

17 Q. Could it be a by-product of carbonyl
18 formation?

19 A. No, I don't believe so.

20 Q. Could it form after a carbonyl had formed
21 on the polypropylene itself?

22 A. I think if carbonyls are forming that
23 certainly you could have one form afterwards, but we
24 aren't getting any carbonyls formed. You've got to
25 keep that in mind now.

1 You're talking about hypotheticals,
2 because it didn't happen because we don't have any
3 carbonyl bonds here.

4 Q. According to your opinions and your
5 reading of this FTIR, there are no C=O bonds,
6 correct?

7 A. Absolutely.

8 Q. Okay. With respect to figure 9, this
9 appears to be mislabeled; is that right?

10 A. I'm sorry?

11 Q. Figure 9, it says blue fiber.

12 A. Yes, sir. The heading of the figure is
13 mislabeled, that's right. It's a typo error. It's
14 not blue. It's clear.

15 Q. And, actually, your FTIR states clear
16 fiber?

17 A. Yes, it does.

18 Q. It's the report itself that is --

19 A. Inconsistent, yeah.

20 Q. And this figure 9 is all of the FTIRs you
21 took on Ms. Shelton's mesh before cleaning as well
22 as after each of the five cleanings that were
23 processed; is that right?

24 A. These are all the FTIRs, one after each
25 step.

1 Q. And were these FTIRs taken at the same
2 point on the mesh, if you know?

3 A. No.

4 Q. They were taken at five different points?

5 A. Yes, sir, by necessity. It's much too
6 small a sample. And, also, to find the exact spot
7 where you took the first or the preceding FTIR after
8 you've run it through a cleaning process, it would
9 be impossible to find the exact spot.

10 Q. Could you mark it with a Sharpie?

11 A. No, sir.

12 Q. Could you make an indent with an "X" like
13 a brand or something?

14 A. I'm not going to indent the sample, no,
15 sir.

16 Q. Sometimes they do get indented on
17 explants, correct, by the surgeons?

18 A. Yes, sir, but that's the surgeon. That's
19 not me.

20 Q. With respect to the after cleaning, the
21 red line on this FTIR, do you see oxidized
22 polypropylene there?

23 A. No, sir.

24 Q. There is actually -- but there is some
25 activity around 1720 to 1700, correct?

1 A. What do you mean by "activity"?

2 Q. So there's a definite peak and valley, and
3 then there is another peak associated with the 1650
4 to 1600 range, correct?

5 MR. HUTCHINSON: Object to the form.

6 THE WITNESS: There's is not enough
7 definitive shape of those curves to make any
8 conclusion from it. You can't draw a
9 conclusion from that.

10 BY MR. BOWMAN:

11 Q. But you do see a peak?

12 A. I see -- I don't see a peak.

13 Q. What do you see?

14 A. I see perhaps the shape of a line moving
15 upward, but no peak.

16 Q. In any event, it's not as we've seen
17 previously, what I was calling a plateau?

18 A. Do what?

19 Q. What I was calling a plateau, that's not
20 present here?

21 A. It doesn't appear to be, no, sir.

22 Q. And with the exception of after
23 cleaning 1, it appears that the peaks are
24 diminishing -- I withdraw question.

25 It appears that the peaks that you

1 identify from the Amide groups are diminishing over
2 time through the cleaning process; is that correct?

3 A. That's correct, sir.

4 Q. And the same is true for the peaks you
5 identify associated with the N-H group around 3200;
6 is that right?

7 A. That is correct, sir.

8 Q. And then on figure 11, we have the Prolene
9 mesh exemplar overlaid with the FTIR clear fibers
10 after the cleaning process of Ms. Shelton's mesh; is
11 that right?

12 A. After step 5, yes, sir.

13 Q. And the two appear to be a little bit off
14 but pretty close to the same; is that right?

15 A. I would think that they are essentially
16 identical, sir. I don't know what you mean by "a
17 little bit off." They are almost identical.

18 Q. So the red, which is the after cleaning
19 for Ms. Shelton, is actually reading a little bit
20 lower, it appears, on every peak and valley than the
21 exemplar mesh; is that right?

22 A. That has to do with the amount of light
23 passing through it, passing through the sample. It
24 doesn't have anything to do with what is there
25 chemically.

1 Q. But it is safe to say that they both --
2 since they're both Prolene and they're both clear
3 that the same amount of light should be passing
4 through?

5 A. Not necessarily. It depends upon where
6 you took them. Remember, this is a circular fiber.
7 If you took the spectra here, the light is passing
8 through here. It's different if you pass through
9 the center.

10 Q. So with respect to figure 13, I don't see
11 it specifically mentioned, but your comparison of
12 the blue fiber to the clear fiber, are you using
13 that to form your opinions for the presence of the
14 clear flakes?

15 A. Well, there was no blue fiber in this
16 sample, but we have a great deal of history between
17 explants where we do have -- this is an unusual
18 explant in the sense that it is all clear.

19 But in our past work, and we have examined
20 approximately 50 of these, a vast majority of which
21 are clear and blue, and the clear and blue flakes
22 are precisely as I've said before. They're
23 translucent in nature, meaning that the flakes on
24 the blue fiber are clear and, therefore, not
25 polypropylene.

1 But I can't use the blue here specifically
2 because I don't have a blue fiber, but I can use the
3 past history to say it would be that those flakes
4 are proteins. And the reason they're proteins is
5 that if you look at the FTIR spectra starting with
6 figure 13A and go to B and C and D and E and then
7 look at those in addition to this light microscopy,
8 you can see that there's a continual decrease in
9 proteins until, finally, you get to figure 13F and
10 there's no proteins at all showing on the FTIR. And
11 that's precisely what you would say. So, therefore,
12 these flakes are proteins.

13 Q. So when you said that you've done this
14 approximately 50 times, the 50 times that you've
15 seen this they have been the result of the cleaning
16 process that you have employed in these cases?

17 A. What do you mean "they have been the
18 result of"? The cleaning process hasn't done
19 anything but clean it. It hasn't changed anything.
20 It hasn't changed what's on the fibers. It's just
21 taking off the proteinaceous composite that we've
22 been talking about for two days.

23 Q. So my question was the 50 times that
24 you've seen this has been the result of testing that
25 you performed -- I'm sorry -- cleaning and testing

1 that you performed on 50 different samples; is that
2 right?

3 A. Just like this, yes, sir.

4 Q. And besides evidence in the peer-reviewed
5 literature of the FTIR, is there anything else in
6 the peer-reviewed literature that leads you to
7 believe that the flakes identified in these light
8 microscopy photographs are protein and not oxidized
9 polypropylene?

10 A. Well, proteins are water soluble, and
11 that's in the peer-reviewed literature. That's well
12 known. That's basic science. And, of course, we've
13 removed this by water, basically a water treatment
14 with sodium hypochlorite to remove flesh.

15 The peer-reviewed literature knows that
16 proteins occur in those regions where we talked
17 about in the spectra. That's extremely well known.
18 It's in textbooks. It's taught to everybody. And
19 we see light microscopy, which is here. That's in
20 the peer-reviewed literature. And you use that as a
21 means of determining what's on the surface of the
22 material, particularly if it's light microscopy.
23 Scanning electron microscopy is in the peer-reviewed
24 literature. It's in textbooks. It's very well
25 known.

1 Everything we've done is peer-review
2 supported, textbooks, teach it in the classes. This
3 is nothing exotic. This is basic science we're
4 talking about here. Basic science shows these flake
5 materials to be proteins.

6 Q. So I'm not sure if we've been going around
7 this for the past two days or not. But those are
8 instrumental analyses, correct?

9 A. Basic science analysis.

10 Q. FTIR, light microscopy and SEMs, those are
11 all instrumental analyses for being able to support
12 conclusions -- I'm sorry.

13 They are instrumental analyses that are
14 run to be able to see results and form conclusions
15 from those results, correct?

16 A. Yes, sir. As a matter of fact, several
17 years ago I taught a class in spectrophotometric
18 identification of organic compounds, FTIR. I taught
19 it to my students, my undergraduates. So this is
20 the basic science that we're using here to show that
21 there is no oxidation present on Prolene.

22 Q. But FTIR itself, it actually measures the
23 bulk of the material. It doesn't measure the
24 surface of the material, correct?

25 A. It measures everything in the material.

1 So if there's oxidation on the surface, you will see
2 it in the FTIR.

3 Q. So the bulk of it includes the surface and
4 the core, correct?

5 A. Restate that, please. The bulk of it?

6 What are you talking about, "it"?

7 Q. The FTIR is going to not only examine
8 what's on the surface but also what's in the bulk of
9 the material, including the core, correct?

10 A. What material? You're talking about
11 Prolene?

12 Q. Anything. It doesn't matter what it is.
13 FTIR, what you put under it, it's going to examine
14 the whole thing?

15 A. If light will pass through it -- if you
16 get a transmission, light will pass through it, yes;
17 if not, you use ATR and you get a surface reading.

18 Q. And your opinions for the flakes are based
19 on FTIR readings at least partially, correct?

20 A. Partially, yes, sir. And the use of the
21 transmission microscopy to make these determinations
22 is supported by peer-reviewed literature as being
23 the best technique.

24 Q. The best technique? I'm not aware of any
25 peer-reviewed literature that tells us what the best

1 technique is to measure surface oxidation on
2 polypropylene, are you?

3 A. Well, you're not a scientist.

Q. I have a biology degree.

5 A. Oh, wonderful.

6 Q. But I guess I'm not a scientist.

7 A. I know it's not my place to ask a
8 question, but if I could, how many FTIRs have you
9 run?

10 Q. I could tell you off the record.

11 (OFF-THE-RECORD DISCUSSION.)

12 BY MR. BOWMAN:

13 Q. So the general idea, Doctor, is that I'm
14 just looking for something that you could tell me
15 that these flakes are definitively protein and not
16 polypropylene, something in the peer-reviewed
17 literature. I understand that the results that you
18 have garnered and put together for Ms. Shelton's
19 report led you to that conclusion. I'm looking for
20 something in the peer-reviewed literature that I
21 could point to to say that the flakes we are seeing
22 are protein and not oxidized polypropylene.

23 A. If you take the FTIR spectras of the
24 samples, as we have done in figures 9 and --
25 figure 9, if you take that FTIR spectra and you go

1 to the Sadtler Library of FTIR Spectra, there is a
2 library of all organic compounds, just like you go
3 to the library and get a book and read it. We'll
4 call them up and say, "We want the FTIR spectra of
5 Prolene, polypropylene." They'll give you this
6 spectra, and we lay that over the samples that we
7 analyze and it will be essentially identical.

8 Q. I understand you've done that with
9 pristine, and I understand that you've done that
10 with the mesh after it has gone through the cleaning
11 process five times.

12 But for Ms. Shelton's case, I'm looking at
13 the flakes that are apparent in B, which is after
14 cleaning process 1. And if we look at the overlay
15 of the FTIR done after cleaning process 1, that's
16 what I pointed out to you earlier where there is a
17 red line and there is this ambiguity where there is
18 a peak that I've identified between 1740 and a
19 little bit under 1700 that I'm trying to understand.

20 I know earlier I talked to you about it,
21 but I'm trying to see how you can line this data up
22 with the data here in B and explain to me that this
23 is not oxidized polypropylene.

24 MR. HUTCHINSON: Object to form.

25 THE WITNESS: Well, it may be an

1 ambiguity to you, but it is not to me.
2 Because if it was oxidized polypropylene, we
3 would see a sharp band occur in the region of
4 1740, and that's the best I can do for you,
5 sir. What I've told you so far is the best I
6 have to offer you.

7 BY MR. BOWMAN:

8 Q. With respect to the SEM images that are
9 associated with Ms. Shelton's case, your report says
10 that the oxidation or degradation of Prolene -- I'm
11 sorry. I am four lines up from the bottom on
12 page 12.

13 It says that oxidation or degradation of
14 Prolene did not occur in vivo. It is further
15 confirmed by the lack of surface pitting on Prolene.
16 Do you see that?

17 A. I do.

18 Q. Are you aware that the defense expert,
19 MacLean, has confirmed that you can have oxidized
20 Prolene without pitting on it?

21 MR. HUTCHINSON: Object to form.

22 THE WITNESS: I'm not aware of that. I
23 have not -- do not remember that. I can't
24 testify to what he said.

25 BY MR. BOWMAN:

1 Q. Will you be referring to Dr. MacLean's
2 report at all when you testify about this case at
3 trial?

4 A. I have not referred to him here.

5 Q. With respect to the extrusion lines that
6 are present on the SEMs in -- and I think I can see
7 them in the SEMs D, E and F of figure 14. Can you?

8 A. Yes, sir.

9 Q. It's your opinion that the presence --
10 because you can see those extrusion lines via SEM
11 that no surface oxidation has taken place on the
12 Prolene; is that right?

13 A. That's one more piece of evidence, yes,
14 sir.

15 Q. And can you point me to some literature
16 describing the extrusion process that would support
17 that opinion?

18 A. Well, I think it would be basic common
19 sense that if you have the same structural
20 configuration of a material that came out of an
21 extruder and went through the process of forming a
22 fiber and then was placed in the human body and then
23 removed and you had this same structural
24 configuration that you had when the material came
25 out of the extruder, that would be information

1 enough and proof enough to say nothing has occurred
2 to it. And that's what we're doing right here, sir,
3 and it doesn't take a peer review to make that sort
4 of analysis. It takes common sense.

5 Q. So you're aware -- I'm sorry. Are you
6 aware that the monofilaments used to make these
7 meshes are extruded through a dye?

8 A. Yes, sir.

9 Q. And have you, yourself, examined the dye
10 used to make these meshes?

11 A. No, sir.

12 Q. Have you, yourself, examined the
13 extrusions, the extrusion process?

14 A. No, sir, not the one -- I know what an
15 extrusion process is. I've extruded material
16 myself. But this specific process we're talking
17 about, I have not witnessed that.

18 Q. Have you cut a monofilament down the
19 middle to check to see if extrusion lines are there?

20 A. Cut it down the middle?

21 Q. Certainly. Take a piece of pristine
22 monofilament and cut it in half, slice it down the
23 middle, and then take the end -- you could even just
24 slice it on the bias and then take the end and see
25 if the extrusion lines are still there. Have you

1 done that?

2 A. Yes, sir -- excuse me. I have not done
3 that, but I have had samples where we have seen
4 those extrusion lines that we've analyzed. We've
5 looked at the cross-sectional ends, and those
6 extrusion lines are there, samples of Prolene that
7 have -- Prolene explants in the past.

8 Q. So does it look like when you chop down a
9 tree and you see the lines going down the middle?
10 Is that what it looks like?

11 A. It looks like extrusion lines, just
12 exactly what you see on the surface if you took a
13 cross-section of it. You know what a cross-section
14 is, of course, biology major?

15 Q. Yes, sir.

16 A. So here's the fiber. You cut it right
17 here. So if you have extrusion lines here and you
18 look at it on the end, then you can see those
19 extrusion lines.

20 Q. I understand. I'm asking about the
21 cross-section. So let's say --

22 A. That is the cross-section that I just
23 described to you.

24 Q. So I'm not sure I understand. So let me
25 see if you can follow my example.

1 You said you -- well, let's say you
2 chopped down a tree. And, you know, some people,
3 they can age the tree by counting the lines going
4 towards the middle. Are you familiar with that?

5 A. I certainly am.

6 Q. So if you get a cross-section of Prolene
7 suture, are you going to see those lines going out?

8 A. No, sir.

9 Q. What are you going to see?

10 A. You're going to see solid polymer until
11 you get to the exterior surface where the lines are
12 formed because that's, you could say, imperfections,
13 but you can't have a perfectly smooth surface that
14 the molten polymer is passing through.

15 So as the molten polymer passes through
16 the extruder, the extrusion -- the extruder has the
17 indentations that form these lines in the exterior,
18 not in the interior. It's not like a tree. The
19 example does not fit.

20 Q. So that's --

21 A. The tree example does not fit.

22 Q. So that's really what I'm looking for, is
23 I'm looking for some literature that you can point
24 me to where I can better understand this extrusion
25 process and the presence of these extrusion lines.

1 A. Well, I suggest that you go look under
2 topic of extrusion and ask these specific questions
3 and see what you find out, and I think that's what
4 you'll find out.

5 Q. Do you have any peer-reviewed literature
6 to support your opinions in this case?

7 A. I haven't looked for any peer-reviewed for
8 that, because it's sheer common sense.

9 Q. Well, there are pressure points on the
10 monofilament as it's extruding, correct?

11 A. Sure, and it's molten.

12 Q. And it's molten?

13 A. Uh-huh (affirmative response). And as it
14 comes out it cools.

15 Q. And it would cool from the outside in,
16 correct?

17 A. That's correct.

18 Q. So why wouldn't that process create
19 extrusion lines from the outside in?

20 A. It does.

21 Q. Are you saying --

22 A. No, no. It would on the surface, but it's
23 solid on the -- the extrusion lines are just so
24 deep, sir. They are taking the shape of the
25 extruder barrel, and the extruder barrel doesn't go

1 all the way into the fiber. They are taking the
2 depth of the extruder barrel, and that's on the
3 outside and only on the outside.

4 Q. Just to close the loop on this, if I
5 wanted to find some literature that would support
6 your opinion, how would I find it?

7 A. I think you would go to a textbook on
8 extrusion, molten polymer extrusion, and take a look
9 at that. That would probably take you where you
10 wanted to go.

11 Q. For your opinion in this case, there's no
12 citation to that in your report; is that right?

13 A. No, sir. That's correct.

14 Q. And with respect to the findings of
15 Dr. MacLean, are you aware that he was able to see
16 extrusion lines and he detect oxidized polypropylene
17 in his findings?

18 A. I don't know what you're talking about,
19 sir.

20 Q. So are you aware that Dunn and Guelcher
21 were also able to oxidize Prolene and see extrusion
22 lines on the polymers that they looked at as well?

23 MR. HUTCHINSON: Objection. Scope.

24 THE WITNESS: I don't know what you're
25 getting at. I have no idea what you're

1 talking about.

2 BY MR. BOWMAN:

3 Q. I'm trying to find support for the
4 opinion, Doctor, that the presence of the extrusion
5 lines --

6 A. I've told you all I have for you, sir.

7 MR. BOWMAN: Well, then that's all I
8 have.

9 EXAMINATION

10 BY MR. HUTCHINSON:

11 Q. Dr. Thames, Chad Hutchinson, counsel for
12 Ethicon and Johnson & Johnson. I have a couple of
13 follow-up questions.

14 You were asked about peer-reviewed
15 literature that supports your opinions that the
16 clear flakes shown in figure 13 are protein and not
17 oxidized Prolene. Do you remember that line of
18 questioning?

19 A. I do.

20 Q. Did you cite any peer-reviewed literature
21 in your general report?

22 A. Yes, sir.

23 Q. And does the literature you cite suggest
24 that proteins adhere to a foreign body implant?

25 A. Absolutely.

1 Q. Does the literature you cite suggest that
2 proteins occur -- the protein adherence occurs
3 immediately?

4 A. Yes.

5 Q. Does the literature you cite suggest that
6 formaldehyde and protein cross-link to create a new
7 polymer?

8 A. Yes.

9 Q. And does the literature you cite suggest
10 that that reaction has been known since 1949?

11 A. Yes.

12 Q. Does the literature you cite suggest that
13 that reaction is basic chemistry?

14 A. Yes.

15 Q. Did Mary Shelton's explant have tissue on
16 it when it was taken out of her body?

17 A. Yes.

18 Q. Is tissue comprised of proteins?

19 A. Yes, sir.

20 Q. Was Mary Shelton's explant then exposed to
21 formaldehyde?

22 A. Yes.

23 Q. Are the light microscopy photographs that
24 we see in figure 13 examples of what is discussed
25 and supported by the peer-reviewed literature?

1 A. Yes.

2 MR. HUTCHINSON: I don't have any
3 further questions. Thank you.

4 FURTHER EXAMINATION

5 BY MR. BOWMAN:

6 Q. I do have a quick follow-up.

7 With respect to the peer-reviewed
8 literature that you cite, Doctor, is there any that
9 you cite with respect to the cross-linking of
10 protein and formaldehyde after it is explanted from
11 the human body? Does that literature cite what
12 happens when Prolene explants are excised from the
13 human body and then placed in formalin?

14 A. The literature doesn't speak specifically
15 to Prolene explants. The literature speaks to the
16 general science that formaldehyde and proteins will
17 react to form a composite. It doesn't matter what's
18 present, whether it's Prolene, whether it's a steel
19 pipe or what.

20 If you have proteins in the presence of
21 formaldehyde, it's going to form a composite. It's
22 well-known basic science over 60 years. It's been
23 known for more than 60 years.

24 Q. Does any of the peer-reviewed literature
25 discuss Prolene or Prolene mesh specific?

1 MR. HUTCHINSON: Are you talking --

2 THE WITNESS: What does your question
3 mean?

4 BY MR. BOWMAN:

5 Q. My question is the peer-reviewed
6 literature on the cross-linking of proteins and
7 formalin.

8 A. Yes, --

9 Q. Does it --

10 A. There is peer-reviewed literature for
11 that. It was known in 1949. It's been printed and
12 published since 1949.

13 Q. I understand. The question I'm asking is
14 if the literature references Prolene or Prolene mesh
15 at all?

16 A. What do you mean "references" it?

17 Q. It's in reference -- the literature, does
18 it reference Prolene and Prolene mesh specifically?

19 MR. HUTCHINSON: You're talking about
20 the literature in general?

21 MR. BOWMAN: I'm talking about the
22 literature that he is using to back his
23 opinion up about this proteinaceous
24 composite.

25 THE WITNESS: I haven't looked for a

1 specific reference to that. I think most
2 people have missed that in this. They have
3 not recognized that science. This composite
4 Prolene -- excuse me -- protein-formaldehyde
5 composite will form around anything. It will
6 form flat. It will form around a fiber. If
7 something were square, it would form around
8 it.

9 It is a general chemical reaction that
10 takes place. And if it happens to be proteins
11 around Prolene, if you put it in formaldehyde,
12 it's going to form. That's the best I can do
13 for you, sir. That is the best. I've stated
14 that over and over today numerous times.

15 MR. BOWMAN: I have nothing further.

16 (CONCLUDED AT 10:59 A.M.)

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1 CERTIFICATE OF COURT REPORTER

2 I, Amy M. Key, CSR, and Notary Public in
3 and for the County of Lamar, State of Mississippi,
4 hereby certify that the foregoing pages, under
5 penalty of perjury, contain a true and correct
6 transcript of the testimony of the witness, as
7 taken by me at the time and place heretofore
8 stated, and later reduced to typewritten form by
9 computer-aided transcription under my supervision
10 and to the best of my skill and ability.

11 I further certify that I placed the witness
12 under oath to truthfully answer the questions in
13 this matter under the power vested in me by the
14 State of Mississippi.

15 I further certify that I am not in the employ
16 of or related to any counsel or party in this
17 matter, and have no interest, monetary or
18 otherwise, in the final outcome of the
19 proceedings.

20 Witness my signature and seal this the
21 _____ day of _____, 2016.

22

23

AMY M. KEY, CSR

24 My Commission Expires May 11, 2020

25

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4 PAGE LINE CHANGE

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2 ACKNOWLEDGMENT OF DEPONENT

3

4 I, _____, do
5 hereby certify that I have read the
6 foregoing pages, and that the same is
7 a correct transcription of the answers
8 given by me to the questions therein
9 propounded, except for the corrections or
10 changes in form or substance, if any,
11 noted in the attached Errata Sheet.

12

13

14

15 SHELBY F. THAMES, PH.D. DATE

16

17

18 Subscribed and sworn
to before me this

19 _____ day of _____, 20 _____.
20 My commission expires: _____

21

22 _____
Notary Public

23

24

25